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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CUTLIFF, YATE KAI RENE	

ART UNIT	PAPER NUMBER
1621	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,374	RONGIONE ET AL.	
	Examiner	Art Unit	
	YATE' K. CUTLIFF	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1 - 22 are pending.

Claims 1 - 22 are rejected.

Response to Amendment

2. The amendment to claims 1, 8, 21 and 22, submitted July 8, 2008 is acknowledged and entered.

Response to Arguments

3. Applicant's arguments, see pages 8 - 9, filed July 8, 2008, with respect to claims 1-7, 21 and 22 have been fully considered and are persuasive. The 102(b) rejection of claims 1-7. 21 and 22, in view of the amendment and arguments, has been withdrawn.

4. Applicant's arguments with respect to claims 8 - 20 have been considered but are moot in view of the new ground(s) of rejection under 35 U.S.C. 103(a) over Saebo et al. (US 6,410,761) and in view of Baltes et al. (US 3,162,758) as set out below.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saebo et al. (US 6,410,761).

9. The rejected claims cover, inter alia. a process to refine a conjugated linoleic acid-containing material comprising: distilling a first ester stream containing esters of conjugated linoleic acids using a distillation apparatus wherein the first ester stream comprises c9,t11 and t10,c12 isomers of the esters of conjugated linoleic acids; and producing a second ester stream enriched in the c9,t11 and t10,c12 isomers of the

esters of conjugated linoleic acids. Dependent clams 2-7 further limit the distillation process.

10. Saebo et al. discloses a novel composition of conjugated linoleic acid (CLA) ester with the isomers c9,t11-octadecanoic acid ester and t10,c12 –octadecanoic acid ester, that were obtained by the direct isomerization of an unrefined linoleic acid. (see column 6, lines 16 - 23). In the process of Saebo et al. after the conjugation reaction the resulting CLA containing composition may be further purified. In the purification process, the resulting CLA is distilled at 190°C in a molecular distillation plant at a vacuum of 10^{-1} to 10^{-2} milibar (0.075 to 0.008 mmHg). Saebo et al. states that the advantage of the purification system is that it takes a shorter time, less than a minute. (see column 10, lines 9 – 37). Example 8 of Saebo et al. discloses the conjugation of safflower fatty acid methyl ester, with Table 14 showing the conjugation yielding a larger distribution of the producing CLA c9,t11 and CLA t10,c12. Even though Example 8 does not show that the conjugated safflower fatty acid methyl ester was further purified after the conjugation reaction, however, the invention of Saebo et al. discloses that purification of the derived novel conjugated linoleic acid-containing compositions may be conducted by molecular distillation. Specifically, Saebo's novel conjugated linoleic acid-containing compositions of a requisite purity with a defined composition having a high percentage of c9,t11 and t10,c12 isomers of CLA . (see column 6, lines 1-6).

Saebo's process fails to disclose the following; that the distilling step includes multiple passes; that the distillation apparatus contains a fractionating column and removal of unconjugated linoleic acid components.

However, the use of multiple passes in the distillation step and the inclusion of a fractionating column in the distillation apparatus, are within the purview of one of ordinary skill in the art of using distillation to purify a composition. Further, the use of a distillation apparatus having a fractionating column is drawn to a routine tweaking, which is dependent upon the impurities being removed from the crude conjugated linoleic acid ester; and a skilled artisan would be motivated to do so in order to improve the purity of the product.

With regard to the removal of unconjugated linoleic acid components, Saebo's process discloses purifying the resulting CLA which contemplates the removal of any undesirable by-products. This limitation is deemed to be obvious absent a showing of unexpected results.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. *(In reOpprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Furthermore, the difference between Saebo et al. and the claimed invention is that it does not teach the invention with particularity so as to amount to anticipation (See M.P.E.P. §2131: "[t]he identical invention must be shown in as complete detail as is contained in the ...claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).).

However, based on the above, Saebo et al. teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be prima facie obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success. See M.P.E.P. § 2143).

11. Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saebo et al. (US 6,410,761) in view of Baltes et al. (US 3,162,658) and further in view of Sachtler (US 5,326,925).

12. The rejected claims cover, inter alia, a process to produce a refined conjugated linoleic acid-containing material, comprising: transesterification of a linoleic acid-containing oil to generate a composition containing linoleic acid esters; isomerization of the composition containing linoleic acid esters to form a first stream containing c9,t11 and t10,c12 isomers of conjugated linoleic acid esters; and distillation of the first stream to produce a second stream enriched in the c9,t11 and t10,c12 isomers of conjugated linoleic acid esters. Rejected claims 10 - 15 disclose the isomerization catalyst, and

isomerization reaction temperature. Rejected claims 9 and 17-20 are drawn to the work up and optimization of the process. Rejected claim 16 discloses the various linoleic acid containing oils used in the process.

13. Saebo et al. discloses process for producing a novel composition of conjugated linoleic acid (CLA) ester with the isomers c9,t11-octadecanoic acid ester and t10,c12 – octadecanoic acid ester, that were obtained by the direct isomerization of an unrefined linoleic acid. (see column 6, lines 16 - 23). In the process of Saebo et al. after the conjugation reaction the resulting CLA containing composition may be further purified. In the purification process, the resulting CLA is distilled at 190°C in a molecular distillation plant at a vacuum of 10^{-1} to 10^{-2} milibar (0.075 to 0.008 mmHg). Saebo et al. states that the advantage of the purification system is that it takes a shorter time, less than a minute. (see column 10, lines 9 – 37). The preferred oil for conjugation are sunflower and safflower oil, other seed oils such as corn, soybean and linseed oils may also be used in Saebo's process. (see column 4,lines 53-54 & lines 57-58).

Saebo's process discloses that the process provides for the formation of the CLA ester by an esterification process involving methanol or ethanol or other branched or straight chain monohydric alcohols. (see column 12, lines 44 - 45 & lines 56 - 57). In the nonaqueous alkali isomerization of the CLA ester of Saebo et al., alkali alcoholate catalyst are used, such as, sodium or potassium ethoxide or their methyl, butyl, or propyl counterparts. (see column 12, lines 50- 55). The isomerization temperature ranges from 130 to 165°C. (see column 9, lines 48 – 49). Example 9 teaches the process for large scale batch production of conjugated safflower fatty acid methyl ester,

wherein the process is a two step process involving the first step of methanolysis (transesterification), and the second step of conjugation (isomerization). Table 15 and 16 disclose the resulting CLA esters having a greater amount of c9,t11 and t10,c12 isomers. (see peak #s 9 and 10). Even though Example 9 does not show that the conjugated safflower fatty acid methyl ester was further purified after the conjugation reaction, the invention of Saebo et al. discloses that purification by distillation of the derived novel conjugated linoleic acid-containing compositions may be conducted. (see column 3, lines 66-67 to column 4, lines 1-13). In Example 9 transesterification is completed sequentially, with transesterification taking place first, side products are removed, then the alcohol and alkali alcoholate catalyst are added to the reactor to conjugate the ester.

Saebo et al. fails to specifically disclose the following: the use of calcium alkoxide salt; the catalyst is a solid or solution in a conjugated alcohol of the alkoxide; the transesterification and isomerization steps are performed in one reaction vessel concurrently; and the transesterification and isomerization steps occur concurrently using dual reaction zones.

However, Baltes et al. discloses an isomerization process for the production of conjugated poly-ethenoid acids and uses the following alkali metals for the alcoholate catalyst: cesium, rubidium, potassium, sodium, lithium, magnesium and zinc. (see column 2, lines 39-45). It is stated that organic alkali metal compounds can be used as catalyst. Also, in Example 1 of Baltes, dried potassium methylate (solid) is used and isomerization and transesterification take place at the same time in one reaction vessel.

Like Saebo et al., Baltes et al fails to list calcium, however, based on the periodic family both references include, one skilled in the art would have been motivated to vary the reaction process, such as by using the calcium as a cation for the alkoxide as a matter of choice based on such factors as the success of other family members in the isomerization reaction. (column 9, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to produce a refined conjugated linoleic acid-containing material as suggested by the process of Saebo et al. and modify the isomerization as suggested by the process of Baltes, to achieve the claimed invention. As disclosed in Saebo et al. motivation for the combination would be to provide a starting point for design of the individual process for the production of the desired compositions containing conjugated linoleic acid.

Therefore, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made, would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

With regards to the processing step that uses a dual reaction zone apparatus for transesterification and isomerization occur concurrently, Sachtler discloses a process in Example 3 that uses a dual zone reaction system in its isomerization process. Even though the process of Sachtler does not involve the isomerization of an identical composition, however, it has been held that a prior art reference be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem

with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See in re Oetiker, 997 F.2d 1443, 24 USPQ 1443 (Fed. Cir. 1992). In this case, applicant is concerned with isomerization of one form of linoleic acid ester to form another form of the linoleic acid ester, while Sachtler was concerned with the isomer 2,3-dimethylbutane. In Sachtler the effluent of a single reaction zone provided the feed for the second reaction zone. As such, it would have been obvious to one of ordinary skill at the time of the claimed invention, knowing that the transesterification and isomerization process can occur sequentially, that a dual reaction apparatus would be successful based on its successful use in the isomerization process of Sachtler. Basically, the transesterification product (linoleic acid ester) provided feed to the second reaction zone where isomerization would take place.

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. In re Young, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). Therefore, this limitation is considered obvious.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 21 and 22 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saebo et al. (US 6,410,761).

16. The rejected claims covers a composition enriched in refined conjugated linoleic acid ester.

17. Saebo et al. discloses a novel composition of conjugated linoleic acid (CLA) ester rich with the isomers c9,t11-octadecanoic acid ester and t10,c12 –octadecanoic acid ester.

18. Applicant is reminded that claims 21 and 22 are in a Product-by-Process format. The PTO takes the following position with respect to Product- by-Process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698,227 USPQ 964, 966 (Fed. Cir. 1985). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221,223 (CCPA 1979).

"The Patent Office bears a lesser burden of proof in making out a case of *prima* facia obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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